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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,831	01/24/2001	David Houze	NOPH/100/JGK	7241

7590 04/22/2005

NOVEN PHARMACEUTICALS, INC.
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,831	HOUZE ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 24-36* is/are pending in the application.

4a) Of the above claim(s) *31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 01/31/2005.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/31/2005 has been entered.

Election/Restrictions

2. Claim 31-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Applicants traverse the withdrawal of claims 31-36 on the ground(s) that the restriction requirement is improper and should be withdrawn. Applicants assert that even if independent and distinct inventions are claimed in the same application, the examiner must examine all claims if the search and examination can be made without

serious burden. The action provides no reasons why the examination of claims 31-36 would be a serious burden.

This is not found persuasive because the two inventions are distinct from each other because claim 1 is directed to a blend of two polymers while claim 31 is directed to composition comprising two polymers that can be polymerized to each other forming copolymer. The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searching claim 1 and 31 may seem to be overlapping, but searching both inventions is extensive because searching the databases for polymer blend is different from searching for composition comprising two polymers that can form a copolymer. A prior art that anticipate a composition comprising two polymers in the form of a copolymer cannot anticipate a composition comprising blend of two polymers. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present two distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18 and 24-30 are included in the prosecution.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-18 and 24-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/287,789. Although the conflicting claims are not identical, they are not patentably distinct from each other because both application claim dermal composition comprising a blend of two acrylic polymers having different functionality and an active agent. The active agent claimed in the present application is generic and encompasses the specific drugs claimed in US application 10/287,789.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The expression "substantially only" is not clearly defining the composition regarding whether or not any other ingredients are present.

Applicants traverse the rejection of claim 11 as being indefinite by arguing that claim 1 is open-ended as to the number of polymers in the polymer composition (a) while dependent claim 11, as presently amended, recites that the polymer composition (a) contains substantially only the first and second acrylic-based polymers. There is no inconsistency between the open-ended language of claim 1 and the more specific language of claim 11. Claim 11 clearly conveys to the skilled artisan the metes and bounds of the claimed embodiment, and therefore satisfies the requirements of 112/2 paragraph.

In response to the above applicant's argument the examiner position is that claim 11 is not clear regarding if the dermal composition comprising only two acrylic polymers and no other polymers are present in the composition, or the claim permits two acrylic polymers as well as other polymers. The specification does not define what is meant by "substantially only" in terms of presence or absence of other polymers and their percentages. Note that claim 1 recites a polymer blend of two or more polymers which include acrylics. Thus, the language of claim 1 permits other polymers, and contradicts with the limitation of claim 11. The examiner suggests deleting "substantially".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-3, 6-9, 11, 12, 14, 15, 17, 18, 24-30 are rejected under 35 U.S.C. 102(a) or 102 (e) as being anticipated by US 5,730,999 ('999).

US '999 discloses a dermal therapeutic system which exhibits prolonged release of the drug comprising at least one pharmaceutical agent combined with poly(meth)acrylates in the form of at least one layer of the therapeutic system. The poly(meth)acrylates are mixture of at least one (meth)acrylic polymer containing functional groups and at least one (meth)acrylic polymer which contains no functional group or only insignificant amount of functional groups (abstract; col.2, lines 66-67; col.3, lines 1-7). The ratio of the functional and non functional polymers ranges between 20:1 to 1:20 depending on the release properties of the pharmaceutical agent and the flow behavior of the product blend (col.3, lines 9-14). The functional polymers contain carboxyl and hydroxyl groups and provided by monomer comprising functional groups in an amount of 10-70% (col.4, lines 1-17). Example of functional acrylic based polymer is copolymers of vinyl monomer (col.3, lines 37-40). Acrylic acid contributes the functional character of the (meth)acrylate polymers (col.3, lines 46-48). Different polymers inherently have different solubility parameters and provide different flux of the same drug. Examples of drugs delivered by the dermal system are nicotine and scopolamine

(col.5, lines 2, 4). The reference disclosed a method of preparing the dermal therapeutic system including stirring the drug and the polymer and drying the premix to a film that impermeable to the drug (col.5, lines 22-39, 55-61).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-18 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,730,999 ('999) in view of US 5,474,783 ('783).

US '999 teaches a dermal therapeutic system which exhibits prolonged release of the drug comprising at least one pharmaceutical agent combined with poly(meth)acrylates in the form of at least one layer of the therapeutic system. The poly(meth)acrylates are mixture of at least one (meth)acrylic polymer containing functional groups and at least one (meth)acrylic polymer which contains no functional group or only insignificant amount of functional groups (abstract; col.2, lines 66-67; col.3, lines 1-7). The ratio of the functional and non functional polymers ranges between 20:1 to 1:20 depending on the release properties of the pharmaceutical agent and the flow behavior of the product blend (col.3, lines 9-14). The functional polymers contain carboxyl and hydroxyl groups and provided by monomer comprising functional groups in an amount of 10-70% (col.4, lines 1-17). Example of functional acrylic based polymer is copolymers of vinyl monomer (col.3, lines 37-40). Acrylic acid contributes the functional character of the (meth)acrylate polymers (col.3, lines 46-48). Different polymers are expected to have different solubility parameters, and one should be higher than the other. Examples of drugs delivered by the dermal system are nicotine and scopolamine (col.5, lines 2, 4). The reference disclosed a method of preparing the dermal therapeutic system including stirring the drug and the polymer and drying the premix to a film that impermeable to the drug (col.5, lines 22-39, 55-61).

US '999 does not expressly teach that the different polymers having different solubility parameters, the percentages of the two polymers in the blend, or haloperidol as the drug to be delivered by the polymer blend.

The percentages of the two polymers in the blend do not impart patentability to the claims, absent evidence to the contrary.

US '783 teaches a transdermal drug delivery system wherein the a blend of at least two polymers having two different solubility parameters adjusts the solubility of a drug in the polymeric blend and thereby modulate the delivery of the drug from the system and through the dermis. The reference discloses a pressure sensitive adhesive composition which is suitable as a matrix for controlled release of a bioactive agent therefrom comprising a blend of a first polymeric adhesive material having a first solubility parameter and a second polymeric adhesive material having a second solubility parameter, the first and second solubility parameters being different from one another (abstract; col.3, lines 36-60; col.6, lines 13-19). The blend therefore has a characteristic net solubility parameter which can be preselected to adjust the saturation concentration of the bioactive agent in the composition and thereby control its release either upward or downward depending upon whether the rate of release is to be enhanced or retarded (col.4, lines 40-45). The transdermal permeation rate is also controlled by varying the relative proportions of the polymers comprising the multiple polymer adhesive system (col.8, lines 3-5). The blend comprising an acrylic based polymer in an amount of 2-96 % (col.4, lines 15-16; col.9, lines 22-26, 51-54). Drugs used in the composition include haloperidol (col.11, line 4). Functional monomers used by the reference are acrylic acid, DURO-TAK and hydroxyl ethyl acetate (col.9, lines 21-54; col.15, lines 50-55). The reference teaches a method of preparation of the transdermal delivery device includes the steps of mixing the ingredients, coating the

formulation onto protective release liner drying solvents in the oven and applying a backing material and release liner (col.15, lines 20-35; col.4, lines 34, 35).

Thus, it would have been obvious for one having ordinary skill in the art at the time the invention was made to provide a dermal composition comprising a blend of two acrylic polymers having different functionalities as disclosed by US '999, and adjust the solubility of a drug in the polymeric blend by manipulating the polymer blend and thereby modulate the delivery of the drug from the system through the dermis as disclosed by US '783, motivated by the teaching of US '783 that net solubility parameter can be preselected to adjust the saturation concentration of the bioactive agent in the composition and thereby control its release either upward or downward depending upon whether the rate of release is to be enhanced or retarded, with reasonable expectation of controlling the rate of delivery of drugs across the skin by preselecting the net solubility parameters of the polymer blend.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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